

### Remarks

Applicant acknowledges the entry of the previous filing as a Request for Continued Examination.

#### Rejections under 112, 1<sup>st</sup> paragraph

The Action rejects claims 73-82 under 112, 1<sup>st</sup> for an alleged lack of written description of the claimed subject matter in the application as filed.

Applicant submits that the Sequence Listing previously filed in the application was a subsequence of the claimed sequences and was filed in error. The sequence listing filed with this response includes the nucleic acid sequence of the complete Organophosphorous Acid Anhydrase (opd) gene that was isolated and sequenced prior to the filing of the original parent application on April 27, 1989.

Applicant admits that the originally filed sequences contained minor errors due to the difficulty in obtaining an accurate gene sequence in 1988-1989 when sequencing of genes was a difficult process that often produced erroneous results. Applicants did possess the isolated nucleic acid sequence, however, and one of skill in the art would have understood Applicants to possess the claimed inventions based on the Specification and the nearly complete nucleotide and amino acid sequences as filed.

For example, at page 7, the Specification states, "The opd gene is isolated by first isolating the native plasmid DNA of an organophosphorus-detoxifying bacterium such as *Pseudomonas diminuta* or *Flavobacterium sp.* (ATCC 27551). The method of isolating and expressing the gene from the isolated plasmid is then described, and the activity achieved in various host cells is shown in Table 1 on page 9. Example 1, beginning on page 20, then describes the cloning and sequencing of the claimed nucleic acid molecule.

Although the reported sequence contained errors, one of skill in the art would understand that the Applicants possessed the claimed molecules.

The claimed invention is therefore fully enabled by the original specification, and furthermore, the specification provides more than adequate written description, since the chemical structure was almost complete, and the molecule was available in a public depository, and was in fact isolated from a bacterial host that was obtained from the public depository as described on page 7.

This issue was addressed by the Court of Appeals for the Federal Circuit in the recent decision, *Enzo Biochem Inc. v. Gen-Probe Inc.* 63 USPQ2nd 1609 (CAFC 2002). In the *Enzo* decision, the court quoted and endorsed the PTO Guidelines for determining when the written description requirement is met:

...the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics... *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo Biochem Inc. v. Gen-Probe Inc.* at 1613

The Court further decided that the written description requirement can be met by a public deposit of material. "... we hold that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes adequate description of the deposited material sufficient to comply with the written description requirement of §112." *Ibid* at 1614

The originally filed specification thus provides more than adequate written description based on the USPTO guidelines by providing almost a complete chemical structure and other physical and/or chemical properties, and functional characteristics when coupled with a known or disclosed correlation between function and structure, as well as providing a description of the availability of the DNA molecule in a public depository.

Applicants submit that the Application is fully compliant with §112, 1<sup>st</sup> paragraph and respectfully request the Examiner to withdraw this rejection.

#### Prior Art Rejections

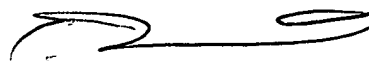
The claims are also rejected under §§ 102 and 103 over US Patent No. 5,484,728 ('728). Applicants submit that the '728 patent is not properly available as prior art to the present claims as Applicants had conceived and reduced the invention to practice in this country prior to the filing date of the '728 as evidenced at least by the publication in May, 1988 of McDaniel et al., Cloning and Sequencing of a Plasmid... *J Bacteriol.* 170(5) 2306-2311, May, 1988. Should the examiner so require, Applicants will submit a declaration according to *In re Katz*, to establish that this paper is the work of the current inventors, removing the '728 patent as prior art.

Applicants thus request that all rejections over the '728 patent be withdrawn.

Applicants submit that in light of the amended Sequence Listing filed herewith and further in light of the preceding remarks, the claims are now in condition for allowance. Such favorable action is respectfully requested.

Respectfully submitted,

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